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TITLE:

Cirrhosis with ascites in the last year of life: a nationwide analysis of factors shaping costs, healthcare utilisation, and place of death; and the impact of day-case paracentesis services.

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BH analysed data and drafted the manuscript. JR assisted with statistical analysis. BG and AP built the combined dataset. JR, KF, AM and JV contributed to study design and critical appraisal of the manuscript.

ABSTRACT

Background:

Liver disease mortality has increased by 400% in the UK since 1970, resulting in rising pressures on acute hospital services, and an increasing need for end-of-life care. We aimed to assess the impact of demographic, clinical, and healthcare factors (including use of day-case large-volume paracentesis (LVP) services), on costs, patterns of healthcare utilisation, and place of death; among a national cohort of patients with cirrhosis and ascites in their last year of life (LYOL).

Methods:

We did a retrospective, nationwide analysis of all patients who died from cirrhosis in England between 2013-15 who required LVP in their LYOL. Outcomes measures were; i)Cost of LYOL, ii)Inpatient days in LYOL, iii)30-day readmission, iv)Occurrence of unplanned hospital death. We examined the effect of 12 independent variables using generalised linear and logistic regression models.

Findings:

13,818 deaths were identified. Mean cost in the LYOL was £21,113, 52.5% of re-admissions occurred within 30 days of discharge, and 74.8% of deaths occurred in hospital. Patients who attended a day-case service within their LYOL had significant associated reductions in cost (-£4,240; 95%CI -£4,829, -£3,651; $p<0.0001$), number of inpatient bed days (-16.68 days; 95%CI -18.13, -15.22; $p<0.0001$), odds of early readmission (odds-ratio (OR) 0.35; 95%CI 0.31-0.40; $p<0.0001$), and odds of dying in hospital following unplanned admission (OR 0.31; 95%CI 0.27,0.34; $p<0.0001$). Among patients enrolled in day-case services, improvements in outcomes correlated with the proportion of LVPs undertaken in a day-case (vs. unplanned) setting. Death from hepatocellular carcinoma (HCC) was also associated with improved outcomes when compared with non-malignant liver diseases.

Interpretation:

The use of day-case services in the LYOL was associated with lower costs, reduced pressure on acute hospital services, and a lower probability of dying in hospital. Wider adoption of day-case models of care may reduce costs and improve outcomes in the LYOL.

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RESEARCH IN CONTEXT PANEL

Evidence before this study

Mortality from liver disease increased by 400% in the UK between 1970 and 2010 (listed as the primary cause of death in 11,575 patients in 2009 in England – accounting for approximately 2% of deaths overall). End-stage liver disease causes an extensive complex of physical and psychological symptoms and is associated with high healthcare costs. Whilst liver transplantation offers the possibility of cure, it is appropriate for a minority of patients. For clinicians, commissioners, and policy makers to design services which meet the needs of patients towards the end of life, an understanding of how demographic, health service, and clinical factors affect healthcare utilisation and resources is required. We aimed to identify studies which assessed factors affecting resource use and health service needs among patients with cirrhosis towards the end of life, with specific focus on the impact of day-case services in patients with ascites. We searched PubMed, Embase and Google Scholar from inception up until 1st March 2017 with the terms (“cirrhosis” OR “ascites”) AND (“cost” OR “readmission” OR “hospitalisation” OR “end of life” OR “palliative care” OR “day case”), and reviewed references of suitable articles. We identified three prospective studies which investigated proactive strategies to improve cost, readmissions and quality of chronic disease management in advanced cirrhosis. Whilst, the largest of these (100 patients) reported significant improvements in cost, readmissions and mortality among patients with ascites followed up proactively through a day-case unit; a similar study of 60 patients failed to demonstrate improvements in hospital admission rates or quality of life. We identified six retrospective cohort studies assessing readmission rates in cirrhosis. 30 day-readmission rates ranging from 12.9 – 40% were reported, with rates increasing among patients with more severe disease. We identified one UK government report which described national data relating to place of death in cirrhosis. We identified three single-centre retrospective observational studies which highlighted that patients with end-stage liver disease seldom received specialist palliative care input. We did not identify any studies which specifically addressed cost, service delivery or outcomes at the end of life among patients with cirrhosis.

Added value of this study

Whilst the potential for day-case services to improve economic and clinical outcomes for patients with cirrhosis has been recognised in small prospective studies, and single centres have described the benefits of such services for patients approaching the end of life, larger scale health economic data surrounding liver disease in the LYOL and day-case services is lacking. To our knowledge, this is the first study to use national data to analyse patterns of hospital usage, cost and place of death outcomes among patients dying with cirrhosis and ascites. We found that patients who attended a day-case LVP service in their LYOL had associated reductions in hospital-based costs, number of inpatient bed days in their LYOL, were less likely to require readmission to hospital within 30 days, and were more likely to die outside of the acute hospital environment (e.g. in their own home or in a hospice). Given the increasing burden placed on acute hospital services by advanced liver disease, and the growing international consensus recognising the need to improve end of life care in this population, this study adds evidence to support the wider adoption and development of day-case services.

Implications of all the available evidence

Decompensated cirrhosis is associated with a high symptomatic burden and financial cost, and exerts significant pressures on acute hospital services in the LYOL. Among patients with cirrhosis requiring LVP, we found utilisation of day-case services to be associated with significant improvements across a range of outcomes in the LYOL. We suggest their expansion may be cost-saving and clinically beneficial. Patients with HCC also had improved outcomes in the LYOL in our study. Palliative care services are rarely accessed for patients with advanced, non-malignant liver disease, which may partly explain this finding. It has been reported elsewhere that patients with benign life-limiting diseases receive inferior access to specialist palliative care services compared to patients with malignancy. A prospective evaluation of day-case services which integrate supportive and palliative care measures into the management of end-stage liver disease is warranted.

INTRODUCTION

Liver disease mortality increased by 400% in the UK between 1970 and 2010, and is the 3rd commonest cause of death in adults of working age.¹ Cirrhosis is associated with a high burden of cost and healthcare utilisation, accounting for more than 150,000 hospital admissions and an estimated \$4 billion annually in the US.² It is associated with higher costs, hospitalisations, and rates of early readmission than other organ failure trajectories.³ Early (within 30 days) readmissions have not been reimbursed in the UK National Health Service since 2010,⁴ and have been associated with a lower quality of patient care.⁵ Early readmission in cirrhosis is related to disease severity, with rates of between 12.1-42.4% reported.⁶⁻⁸ Among patients with decompensated cirrhosis a US study reported a 30-day readmission rate of 37%, with associated costs of over \$20,000 per admission.⁷

The need to improve end-of-life care for patients with liver disease has been recognised internationally.^{9,10} Patients who are unsuitable for organ transplantation are unlikely to receive specialist palliative care,^{11,12} and rates of death occurring in hospital (a proxy measure for quality of end-of-life care) are significantly higher in cirrhosis than for other conditions. In England, over two-thirds of deaths secondary to liver disease (over 80% for alcohol related liver disease – ArLD) occur in hospital, compared with under 40% for cancer.¹³ Given that death in hospital may represent the preferred (and most clinically appropriate) option for some patients, crude place of death has however been criticised as an outcome measure.¹⁴

Ascites is the most frequent complication of cirrhosis, and the commonest reason for hospital admission.¹⁵ It is associated with high rates of disability and healthcare utilisation.¹⁶ Once refractory to medical treatment (refractory ascites – RA) median transplant free survival is 6 months.¹⁷ In severe ascites, large volume paracentesis (LVP) is commonly required to achieve symptomatic relief. LVP traditionally required ad-hoc inpatient admission, however, more recently in the UK, day-case LVP services have been established. Day-case units are typically based within acute hospitals, and run by specialist hepatology nurses within wider,

consultant-led teams.¹⁸ Small observational studies have reported their potential for cost saving and improved patient care,¹⁹ however day-case LVP services are limited to certain UK centres. Studies reporting uniformity of day-case service provision in England are lacking, however, the Lancet standing commission on liver disease has described a wider ‘post-code lottery’ of specialist services for patients with liver disease in the UK.¹

Data exploring the impact of liver disease on resource use and patient outcomes towards the end of life are necessary to inform appropriate allocation of funding, and improve existing models of clinical care. High-level studies detailing the LYOL in cirrhosis are not described in current literature, resulting in a paucity of evidence surrounding resource allocation and optimum service design. Furthermore, national data assessing the impact of day-case LVP services on wider health economic outcomes have not been described. We report healthcare costs, patterns of service use, and place of death outcomes from a nationwide cohort of patients who died from cirrhosis with ascites in England between 2013-2015. We explore the relationship between demographic, clinical, and service factors (including enrolment in day-case LVP programmes); and economic and healthcare outcomes in the LYOL.

METHODS

We identified deaths occurring secondary to liver disease in England between 2013-2015 from the Office for National Statistics (ONS) mortality database. Cause of death was determined by death certificate data, with only deaths relating specifically to liver disease and cirrhosis (as defined by World Health Organisation International Statistical Classification of Diseases and Related Health Problems (ICD-10) code)²⁰ included in analysis. We linked unique patient identifiers to the English Hospital Episode Statistics (HES) database. LVP procedures were identified through descriptive procedure codes (Office of Population Censuses and Surveys Classification of Interventions and Procedures, version 4).²¹ Patients who underwent one or more LVP in the LYOL were included in analysis. Healthcare resource group (HRG) codes from each hospital episode in the LYOL were linked to their associated national tariff from the 2014-15 financial year to provide an estimate of cost (supplementary table 4, appendix page 6 - shows the most commonly occurring HRG codes and tariffs within dataset).²² Case selection is summarised in supplementary figure 1 (appendix, page 1).

We determined outcome measures prior to analysis, which were defined as follows; 1)Cost: cumulative cost of all episode tariffs within the LYOL; 2)Inpatient bed days: number of nights in LYOL spent as an inpatient in an acute hospital; 3)Early unplanned readmission (EUR): occurrence of one or more unplanned admission within 30 days of discharge from an inpatient episode within the LYOL; 4)Unplanned hospital death (UHD): the occurrence of death in hospital during an unplanned admission. Admission type (unplanned vs. elective) was included in this outcome measure due to previous criticism of crude place of death as a proxy for quality in end-of-life care.¹⁴

To investigate the impact of day-case LVP services, we categorised cases into two care groups; day-case care (DC) and unplanned care (UC). Patients who attended a day-case LVP service at least once in their LYOL were classified as DC, whilst patients who underwent all LVP procedures in their LYOL during an

unplanned admission were classified as UC. Among patients enrolled in day-case services, we investigated whether the increased use of such services related to proportional changes in outcomes. To assess this, the number of LVPs undertaken as a day-case, as a proportion of the total number of LVPs required in the LYOL (day-case plus unplanned procedures), was calculated (paracentesis ratio).

For each outcome variable, we controlled for demographic factors (sex, ethnicity, age at death, index of multiple deprivation quintile (a relative measure of socio-economic deprivation based on postcode)²³, year of death), clinical factors (cause of death, place of death, time to death (days between index presentation in the LYOL and death)), and healthcare service factors (care group, paracentesis ratio (DC group only), number of LVP procedures in LYOL, number of non-LVP episodes in LYOL). In patients with multiple liver conditions (e.g. HCC on background of hepatitis C), we attributed a singular aetiology based on hierarchical appearance within the death certificate. Demographic data were approximately normally distributed and parametric tests were used to determine differences in baseline values between care groups (unpaired t-tests to compare continuous variables, and chi-squared tests to compare categorical outcomes).

As is commonly the case, data on costs and resource use (bed days) exhibited significant right skew. To address this, a generalised linear model (GLM) was selected. GLMs allow extension of the linear modelling framework to dependent variables that are not normally distributed. A Gaussian family was specified based on the modified Parks test, with canonical log link function.²⁴ Multivariable logistic regression was used to estimate adjusted odds ratios (OR) for having any EUR in the LYOL and UHD. Among patients enrolled in a day-case LVP service, we assessed the impact of the paracentesis ratio on outcomes using identical methodology. For continuous co-variables within regression models, post-hoc analysis confirmed assumptions of linear regression were met. Statistical analysis was carried out using Stata 14.2 (StatCorp, TX, USA).

Role of the funding source

The funder of the study had no role in study design, data collection, data analysis, data interpretation, or writing of the report. The corresponding author had full access to all the data in the study, and all authors had final responsibility for the decision to submit for publication.

RESULTS

Unadjusted results

13,818 people who died from liver disease and underwent LVP within their LYOL were identified, representing 30.8% of all liver related deaths in England between 2013-2015. 73,858 admissions and 127,495 unique episodes were included in analysis. Mean age at death was 61.9 (standard deviation (SD) 13.0). 9,125/13,818 (66.1%) of the population were male, and 11,512/13,818 (83.3%) of white British ethnicity. ArLD was the most common cause of death (6,376/13,818, 46.1%). Deprivation was positively skewed, with 4,059/13,818 (29.4%) of deaths occurring within the most deprived economic quintile compared with 1,869/13,818 (13.5%) within the least deprived.²³ The mean total cost of hospital care per person in the LYOL was £21,113 (SD 16,881), equating to an average cost of £7,718 per month of care received (i.e. mean cost per month between index presentation in the LYOL and death). A mean of 35.2 days (SD 33.4) were spent as a hospital inpatient in the LYOL, equating to a mean of 33.2% of days between index presentation in the LYOL and death. Excluding index admissions, 17,888/34,068 (52.5%) of emergency admissions within the LYOL occurred within 30 days of a previous discharge. 10,045/13,818 (72.7%) of deaths occurred during an unplanned hospital admission. Of the 2,464/13,818 (17.8%) of patients who only had one admission in the LYOL, 2,063/2,464 (83.7%) died during that admission. Unadjusted comparison between care groups demonstrated a lower proportion of ArLD, a higher proportion of HCC, a higher LVP burden, and a longer average time between index presentation and death in the day-case group. Table 1 summarises unadjusted results and population demographics, and provides baseline comparisons of care groups.

Cost in the LYOL

Table 2 summarises GLM outputs for cost and bed days. Variables with the highest associated reductions in cost were HCC (-£4,505; 95%CI -£5,137, -£3,872; $p < 0.0001$), enrolment in a day-case LVP service (-£4,240; 95%CI -£4,829, -£3,651; $p < 0.0001$), and death occurring outside a hospital or care home (death at

home; -£2,275; 95%CI -£2,871, -£1,679; $p<0.0001$, death in a hospice; -£1,250; 95%CI -£2,143, -£357; $p=0.006$). Cost correlated positively with rising socio-economic deprivation, increasing LVP requirement, and number of hospital episodes.

Inpatient bed days

The variables associated with the fewest inpatient bed days in the LYOL were enrolment in a day-case LVP service (-16.98 days; 95%CI -18.45, -15.51; $p<0.0001$), HCC (-10.30 days; 95%CI -11.88, -8.72; $p<0.0001$), and death at home (-3.87 days; 95%CI -5.35, -2.38; $p<0.0001$). Death occurring in a care home was associated with significantly more inpatient bed days in the LYOL (18.37 days ; 95%CI 16.01, 20.73; $p<0.0001$).

Early unplanned readmission

Adjusted odds ratios, demonstrating the effect of independent variables on the probability of EUR and UHD, are shown in table 3. Enrolment within a day-case LVP service was the principal factor affecting the probability of EUR within the LYOL (OR 0.35; 95%CI 0.31,0.40; $p<0.0001$). Non-white ethnicity (OR 1.22; 95%CI 1.08, 1.36; $p=0.001$) and viral liver disease (OR 1.42; 95%CI 1.10, 1.83; $p=0.006$) were associated with an increased probability of EUR, however the magnitude of their effect was smaller. As LVP requirement increased, so too did risk of EUR within the LYOL. The differential impact of day-case care on odds of EUR in the LYOL reduced as LVP requirement increased (figure 1).

Unplanned hospital death

Death caused by HCC and enrolment in a day-case LVP service and were the factors most strongly associated with a reduced odds of UHD (HCC: OR 0.16; 95%CI 0.14,0.18; $p<0.0001$; day-case care: OR 0.31; 95%CI 0.27,0.34; $p<0.0001$;). Probability of UHD increased with worsening socio-economic deprivation, non-white ethnicity, increasing LVP requirement, and a younger age at death. Supplementary

figure 2 (appendix page 2) demonstrates the relationship between cause of death and age, on the adjusted probability of UHD.

The impact of increasing the proportion of day-case care

Among patients enrolled in a day-case LVP service, the relationship between the proportion of care received in a day-case setting (paracentesis ratio) and aforementioned outcomes was explored. A summary of outputs from the two GLM models from this subgroup (cost, inpatient bed days) is shown in supplementary table 1 (appendix page 3), and the two logistic models (odds of i)EUR, ii)UHD) in supplementary table 2 (appendix page 4). Figure 2 demonstrates graphically the relationships between paracentesis ratio and outcomes. An increasing proportion of day-case care (i.e. a higher paracentesis ratio) correlated with significant improvements in each outcome.

DISCUSSION

This is the first study to use national level data to analyse cost, patterns of hospital usage, and place of death among patients dying from cirrhosis. We demonstrate high economic and health service burdens in the LYOL, and highlight strong associations between improved outcomes and day-case models of care. Our costings quote the sum of all potentially chargeable HRG tariffs in the LYOL, however the true cost to hospitals is likely to be substantially higher. 52.5% of repeat admissions occurred within 30 days of prior discharge – none of which would have been reimbursed within the NHS.⁴ The wider opportunity costs to hospitals, including staff time, bed capacity, and lost revenue from reimbursable admissions, are also not reflected in these data. The early re-admission rate of 52.5% is higher than other estimates in the literature,⁶⁻⁸ which may relate to increased disease severity within the LYOL.

Attendance at a day-case service was associated with highly significant improvements in all outcomes. Compared to patients receiving exclusively unplanned care, enrolment in a day-case LVP service within the LYOL was associated with lower healthcare costs, fewer inpatient bed days, a lower likelihood of EUR, and a reduced probability unplanned hospital death. Furthermore, among patients attending day-case units, a ‘dose-response’ relationship was seen; with improvements in outcome correlating with the proportion of LVPs performed in a day-case setting. Our findings are consistent with the associated reductions in cost and bed-occupancy reported by individual UK centres which have introduced nurse-led LVP services.¹⁹ In addition to cost and resource benefits, Chivenge et al also describe the potential for day-case LVP services to proactively introduce palliative care and advance care planning for patients in whom curative options have been exhausted.¹⁸ Such elements of care may have contributed to the reduced incidence of UHD in the day-case group.

The potential for day-case services to improve outcomes in patients with cirrhosis has previously been described. Morando et al prospectively randomised 100 patients with cirrhosis and RA to either ‘standard

outpatient care’ or ‘care management check-up’ groups following discharge from their index admission.²⁵ Patients in the intervention group were proactively followed up through a day-case unit, receiving regular planned multidisciplinary input. Significant improvements in costs, readmissions and mortality were observed over the one-year follow up period. An Australian study, which prospectively assigned 60 patients with cirrhosis to a chronic disease management programme or usual care, however, failed to demonstrate improvements in admission rates or quality of life.²⁶ Within our study, baseline differences between day-case and unplanned care groups undoubtedly exist; notably the reduced prevalence of ArLD, higher LVP requirement, and longer time between index presentation and death in the day-case group. Whilst multivariable regression corrects for these factors statistically, the two groups may exhibit fundamentally differing illness trajectories and healthcare behaviours. Nonetheless, the substantial and significant improvements associated with day-case models of care provide compelling evidence to support their wider adoption across the UK. Whilst an investment in services, for example through growth, training, and development of the hepatology specialist nurse workforce, may be required to achieve this; the potential longer term economic and clinical benefits are clear.

Deaths caused by HCC were associated with lower costs, fewer inpatient bed days, and a highly significant reduction in the odds of unplanned hospital death when compared to deaths caused by non-malignant liver diseases. Whilst the reasons for this cannot be extrapolated from our data, potential explanations are nonetheless worthy of discussion. Extensive and unresolved supportive and palliative care needs have been widely reported among patients dying from non-malignant organ failures.²⁷ Despite shifts in national policy and legislature, inequities in the availability of specialist palliative care services for patients with non-malignant disease are recognised, and a disproportionately low percentage of deaths occur in a hospice environment.²⁸ Palliative care services are seldom accessed by patients with non-malignant liver disease, with interventions typically limited to inpatient end-of-life care for a minority of patients.^{11,12} Timely palliative care is cost effective and can curtail futile and expensive interventions at the end of life.²⁹ Whilst definitions of curability and utilisation of ‘best supportive care’ approaches are clearly embedded into

international guidelines for the management of HCC,³⁰ prediction of irrevocable decline in non-malignant liver disease is arguably more difficult. For patients with non-malignant liver diseases who have a poor but uncertain prognosis, wider utilisation of novel models of care which afford parallel access to both disease modifying interventions and palliative care may be required.^{10,31}

Consideration of inherent limitations within our data is necessary to inform its interpretation. Issues with the accuracy and completeness of death certificate data have been reported.³² Furthermore, HES are based on coding typically performed by non-clinical staff, which may have adversely affected data quality. One may have expected the proportion of patients with cirrhosis undergoing LVP in the LYOL (30.8%) to be higher (ascites develops in ~60% of patients with compensated cirrhosis over 10 years).³³ A nationwide, US study of hospital admissions related to cirrhotic ascites reported that diagnostic paracentesis was undertaken in 51% of cases,³⁴ however, there are no comparable studies with which to compare incidence of LVP. Although LVP is only required in cases of severe ascites, omissions in HES coding may have resulted in some patients not being captured within our dataset. Disease severity (e.g. model for end-stage liver disease score), and co-morbidity have been shown to independently impact upon readmission rates and resource use.^{7,8} We used data from the LYOL among a cohort who died from cirrhosis, indicating a universally advanced disease stage; however, our dataset does not include these specific factors, nor the wider facilities available at individual healthcare institutions, which weakens the level of adjustment. Nonetheless, to our knowledge, this study represents the largest analysis of cost and healthcare utilisation in the LYOL among patients with cirrhosis to date, and is unique in its consideration of outcomes at the end of life. It provides insight into clinical, demographic, and organisational factors impacting resource use and care quality, and affords powerful data to support the cost-effective transformation of current services.

This study raises many questions which require further exploration. The benefits associated with day-case care could plausibly be enhanced through the redirection of services away from the acute hospital and towards the community, particularly towards the end-of-life. Whether such benefits would be offset by the

‘economies of scale’ afforded by secondary care is however debateable, and pilot studies exploring potential models of nurse-led, community care are warranted. These may include integration of palliative care measures in appropriately identified patients. Our study focussed on day-case services for patients requiring LVP, however the development of similar models of care for patients with other complications of cirrhosis also merits attention. Among patients enrolled in day-case services, we demonstrate associations between an increasing proportion of procedures performed in a day-case setting (paracentesis ratio), and improved outcomes in the LYOL. The paracentesis ratio may reflect an auditable surrogate of care quality, however prospective assessment and validation of this measure is required. Finally, the 14.9% of patients who died during their only hospital contact was alarming, and suggestive of sub-optimal and inequitable access to care among a significant minority of patients with cirrhosis. Targeted models of screening for cirrhosis in high risk populations may be required in the future to redress this inequality.

CONCLUSION

The typical model of secondary care focusses upon reactive responses to urgent issues, as opposed to proactive management of chronic disease.³⁵ Cirrhosis is associated with particularly high symptomatic and economic burdens, and represents a condition where changing models of care delivery may confer considerable benefit; particularly towards the end of life. Day-case services are associated with lower costs, reduced pressure on acute hospital services, and better outcomes towards the end of life, and are likely to reflect a superior model of care for patients with ascites.

DECLARATION OF INTERESTS

The authors declared no conflicts of interest

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